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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,555	01/31/2001	Mitchell Anthony Delong	7996	4966
23409	7590	08/31/2006		
MICHAEL BEST & FRIEDRICH, LLP 100 E WISCONSIN AVENUE MILWAUKEE, WI 53202				
			EXAMINER BADIO, BARBARA P	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/774,555

Applicant(s)

DELONG ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

**Final Office Action on the Merits of a RCE**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Status of the Application***

2. Claims 1-4 and 6-21 are pending in the present application. The instant claims stand rejected as indicated below.

***Claim Objections***

3. The objection to claim 5 under 37 CFR 1.75(c), as being of improper dependent form is made moot by the cancellation of the instant claim.

***Claim Rejections - 35 USC § 102***

4. The rejection of claim 5 under 35 USC 102(b) over *Wos et al.* (WO 99/12895) is made moot by the cancellation of the instant claim.

***Claim Rejections - 35 USC § 103***

5. The rejection of claims 1-6, 8, 11 and 13-21 over *Wos et al.* (WO 99/12895) is withdrawn.

6. Claims 1-4, 6-10 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wos et al. (WO 99/12896).

Wos et al. teaches a generic group of prostaglandin F analogs useful in the treatment of bone disorders and glaucoma (see the entire article, especially Abstract; pages 6-10, Compounds; Examples 1-50). The reference teaches various carriers including talc, polyethylene glycol, water, sesame oil and glycerin (see page 28, 3<sup>rd</sup> paragraph); various routes of administration including topical application (see page 28, 4<sup>th</sup> paragraph; page 29, 3<sup>rd</sup> paragraph; page 31, Example C) and various dosages depending on the condition being treated, the severity of said condition as well as the route of administration (see page 29, last paragraph – page 30 1<sup>st</sup> paragraph).

The instant claims differ from the reference by reciting compounds not exemplified by the reference, i.e., compounds wherein R<sup>3</sup> and R<sup>4</sup> are independently OR<sup>10</sup>, SR<sup>10</sup> and OH; with the proviso they are not both OH. However, Wos et al. teaches an equivalent between H, alkyl, OR<sub>10</sub>, SR<sub>10</sub> and OH at the same position, i.e., R<sup>3</sup> and R<sup>4</sup>, with the exception that both are not OH (see page 7, 2<sup>nd</sup> paragraph). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the exemplified compounds forming compounds as taught by the reference wherein each of R<sup>3</sup> and R<sup>4</sup> are independently selected from OR<sub>10</sub>, SR<sub>10</sub> and OH. The motivation would be based on the desire by the skilled artisan in the art to make additional compounds that would be useful in treating diseases such as bone disorders and glaucoma as taught by Wos et al.

Claim 18 further differs from the reference by reciting specific propellants known in the art. However, the formulation of topical preparations and the combination of various excipients, including propellants are within the level of skill of the ordinary artisan in the pharmaceutical art (see for example, US 5,716,609, col. 5, lines 28-34; US 5,641,494, col. 4, lines 48-59). Thus, the utilization of the specific propellants recited by the instant claim would have been prima facie obvious to the skilled artisan in the art at the time of the present invention.

7. Claims 1-4 and 6-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wos et al. (WO 99/12895) in view of Wos et al. (WO 99/12896) and/or Delong et al. (WO 99/12898).

Wos et al. teaches a generic group of prostaglandin F analogs useful in the treatment of bone disorders and glaucoma (see the entire article, especially Abstract and pages 6-8, Compounds; Examples 1-42). The reference teaches various carriers including talc, polyethylene glycol, water, sesame oil and glycerin (see page 32, 1<sup>st</sup> paragraph); various routes of administration including topical application (see for example, 32, 5<sup>th</sup> paragraph and Examples B and C) and various dosages depending on the condition being treated, the severity of said condition as well as the route of administration (see page 33, 4<sup>th</sup> and 5<sup>th</sup> paragraphs).

The instant claims differ from the reference by reciting compounds wherein R<sub>3</sub> and R<sub>4</sub> are independently OR<sup>10</sup>, SR<sup>10</sup> and OH; with the proviso they are not both OH. However, each of Wos et al., '896 and Delong et al., '898 teaches prostaglandin F

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analogous useful in the treatment of bone disorders and glaucoma (see each in its entirety, especially the Abstracts; '896, pages 6-8, Compounds; Examples '898, pages 6-8, Compounds) and an equivalent between H, alkyl, OR<sub>10</sub> and SR<sub>10</sub> (see '896, page 7, 2<sup>nd</sup> paragraph; '898, page 7, 1<sup>st</sup> paragraph). Therefore, modification of the compounds taught by Wos et al., '895 by replacing the R<sub>3</sub> and R<sub>4</sub> groups in the exemplified with OR<sup>10</sup> and/or SR<sup>10</sup> as taught by the '896 or '898 would have been obvious to the skilled artisan in the art at the time of the present invention because he would have the reasonable expectation that said would result in compounds useful in the treatment of bone diseases and glaucoma as taught by each of the above-cited prior art. The motivation would be based on the teaching of equivalence between H, alkyl, OR<sup>10</sup> and SR<sup>10</sup> at similar position as taught by Wos et al., '896 and Delong et al., '898.

Claim 18 further differ from the reference by reciting specific propellants.

However, each of the recited propellant is known in the art. In addition, the formulation of topical preparations and the combination of various excipients, including propellants are within the level of skill of the ordinary artisan in the pharmaceutical art (see for example, US 5,716,609, col. 5, lines 28-34; US 5,641,494, col. 4, lines 48-59). Thus, the utilization of the specific propellants recited by the instant claim would have been prima facie obvious to the skilled artisan in the art at the time of the present invention.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Telephone Inquiry***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB

August 28, 2006